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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,120	12/14/2000	Francine Joly	GEI-082	2156

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/10/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,120

Applicant(s)

JOLY ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2001 and 18 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,25-29 and 33-35 is/are rejected.
- 7) ☒ Claim(s) 23,24,30-32 and 36-39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges receipt of paper numbers 9 and 10 filed 11/15/01 and 01/18/02 respectively.

Applicant's arguments with respect to office action mailed 07/25/01 have been considered but are moot in view of the new ground(s) of rejection and in view of the amendment to the claims that were not considered in the last office action. These amendments are considered in this action.

Claim Numbering

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 20-23 were renumbered 18-21.

Misnumbered claims 24-26 have been renumbered 22-24.

Misnumbered claims 27-41 have been renumbered 25-39.

Thus, by the amendments in paper numbers 6, 61/2, 9 and 10, the pending claims are 22-31. Examiner respectfully requests that applicants provide the pending claims reflecting all amendments in an appendix.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting release of inflammation or allergic mediators, does not reasonably provide enablement for preventing release of inflammation or allergic mediators.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The asserted utility is not believable on its face. It is not known how a method/process wherein a claimed composition can be administered to prevent release of inflammation or allergic mediators. It is not known how the release of allergic mediator or inflammation mediator can be precisely predicted as to when the release will occur and to administer the composition of the application to effectively **prevent the release**.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

- 1) Breadth of claims.
- 2) Nature of invention.
- 3) State of prior art.
- 4) Level of ordinary skill in the art.
- 5) Level of predictability in the art.

- 6) Amount of direction and guidance provided by the inventor.
- 7) Existence of working examples
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The present invention is in the field of reducing or inhibiting release of inflammation or allergic mediators. The state of the art is what prior art knows about the invention. There is no known art wherein a certain composition is administered to successfully prevent release of inflammation or allergic mediators. The level of ordinary skill is high but only in the art of inhibiting, reducing release of inflammation or allergic mediators. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by the applicants. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicants. The amount of direction and guidance provided by the applicants is limited to reduction and inhibition. There is no evidence in the specification that established correlation between the experiment and the claimed utility. See Ex parte Mass, 9 USPQ2d 1746, 1987. The quantity of experimentation required to use the method/process as claimed in the instant invention, based on applicants' disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of in-vivo experiments to **prevent the** release of inflammation or allergic mediators. The disclosure does not provide adequate guidance to the person of ordinary skill to practice the invention as claimed.

Inhibiting or inhibition or reducing or lessening may be used in place of "preventing".

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is indefinite because the claim recites "and/or" in line 1. See *Ex parte* Anderegg 51 UAPQ 66

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 22, 25-29 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 404126057.

JP 404126057 discloses a composition comprising seawater, adequate amounts of water, saccharides, a fruit juice, proteins, an amino acid, vitamins, vegetable extracts, carbonic acid, a flavoring agent, a sweetener, lactic acid and lactic acid bacteria, honey, nicotinic acid, sodium glutamate, a sour agent, a thickener, a colorant, a stabilizer, an emulsifying agent, fiber, fats, ash, arginine, caffeine, preservative and caramel (abstract). Future intended use does not patentably distinguish a composition claim over the prior art.

Amino acids including the basic amino acids have amino groups/moieties. Also, salts of amino acids are obvious variants of amino acids. The abstract of JP 404126057 is silent on

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amount of seawater and amino acid. In the absence of unexpected results the recited amounts are not inventive over the prior art. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of JP 404126057. One of ordinary skill in the art would have been motivated to prepare the composition of JP 404126057. One having ordinary skill in the art would know routine ways of optimizing the amounts of sea water and amino acids in the composition that would generate the desired effect.

Claim Objections

Claims 22-24 are method claims and depend from composition claim. Method claims cannot depend from composition claims. Correction is required.

8. Claims 31, 32 and 37 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 31, 32 and 37 do not further limit claim 25, a composition claim, because obtaining sea water from the ocean or sea is and filtering or sterilizing or adjusting the pH do not further limit the composition.

9. Claims 30, 36, 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification including the claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374.

The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
April 5, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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